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09/733,079	12/11/2000	Gunnar Andersson	215547.01301	1940

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EXAMINER	
PATTERSON, MARC A	
ART UNIT	**PAPER NUMBER**
1772	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/733,079	ANDERSSON ET AL.	
	Examiner	Art Unit	
	Marc A. Patterson	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-14,16-22 and 26-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-14,16-22 and 26-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

NEW REJECTIONS

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1 – 9, 11 – 14, 16 – 17, 20 – 22 and 26 – 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) view of Collette et al (U.K. Patent 2001080) and Fujii et al (European Patent No. 0838321) and Miki et al (U.S. Patent No. 4,089,913).

With regard to Claims 1, 11 – 14 and 16 – 17, Heilmann et al disclose a film comprising three layers: an outer layer, supporting layer and a middle layer bctween the two layers (the middle layer is termed the central layer; column 3, lines 31 - 32); the supporting layer is therefore an inner layer, opposite the outer layer; the outer layer comprises polypropylene alone (column 5, lines 30 – 35), therefore 100% polypropylene materials, and the middle layer comprises a blend of polypropylene and styrene ethylene butylene styrene block copolymer (column 5, lines 43 - 45), and the inner layer comprises up to 70% of the material of the middle layer (column 5, lines 46 – 50); the film is sterilized with hot steam at 121 degrees Celsius (column 9, lines 14 - 16); the layers comprise polypropylene, as stated above, and therefore comprises polypropylene homopolymer; Heilmann et al do not disclose the necessary use of further components, therefore Heilmann et al disclose an outer layer which consists of 100%

polypropylene homopolymer and a middle layer which consists of a blend of polypropylene and styrene ethylene butylene styrene, and an inner layer which consists of up to 70% of the material of the middle layer. Heilmann et al fail to disclose a multilayer film that has no yield point.

Collette et al teach a polypropylene (page 1, line 5) that shows no yield point, and therefore displays no measurable yield point (page 1, line 54) for use in the making of films (page 4, lines 18 - 19) for the purpose of obtaining films having high extensibility (page 4, line 25). One of ordinary skill in the art would therefore have recognized the advantage of providing for the polypropylene of Colette et al which displays no measurable yield point, as the polypropylene in Heilmann et al, depending on the desired extensibility of the end product. It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a polypropylene which displays no measurable yield point in Heilmann et al in order to obtain a film having high extensibility as taught by Colette et al, thus obtaining a multi – layer film having no measurable yield point; the film taught by Collette et al displays no yield following exposure to temperature above l21 degrees Celsius (after hot compression molding at 180 degrees Celsius; page 9, lines 51 - 55) and therefore displays no yield following sterilization at 121 degrees Celsius. Heilmann et al do not disclose that styrene ethylene butylene styrene block copolymer has no yield point, but Miki et al teach that elastomeric materials have no yield point (column 13, lines 1 – 20; Table 15). The styrene ethylene butylene styrene block copolymer, like the polypropylene taught by Collette et al, therefore has no measurable yield point, because styrene ethylene butylene styrene block copolymer is an elastomer.

Heilmann et al also fail to disclose a film having an elasticity modulus of the middle layer that is less than 100 MPa and an elasticity modulus of the material of the outer layer that is greater than 400 MPa.

Fujii et al teach a polypropylene film (sheet; page 29 - 30) having an elasticity modulus (elastic modulus; page 4, lines 31 - 32) of 20 to 1000 MPa (page 2, line 39) for the purpose of obtaining a film that is soft and transparent (page 4, line 29). One of ordinary skill in the art would therefore have recognized the advantage of providing for the modulus of elasticity of 20 to 1000 MPa of Fujii et al in the layers of Heilmann et al and Colette et al, which comprises a polypropylene film, depending on the desired softness and transparency of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for an elasticity modulus (elastic modulus', page 4, lines 31 - 32) of 20 to 1000 MPa in Heilmann et al and Colette et al in order to obtain a film that is soft and transparent as taught by Fujii et al. The range of elasticity moduli of the layers would therefore include the claimed ranges of less than 100 MPa and greater than 400 MPa.

Heilmann et al also fail to disclose a middle layer that consists of at least 60% by weight polypropylene and an inner layer that consists of 30 to 10% by weight styrene ethylene butylene styrene block copolymer. However, Heilmann et al disclose the selection of the amounts of polypropylene and styrene butylene ethylene styrene in the middle layer depending on the desired softening temperature (column 5, lines 35 – 42). Therefore, one of ordinary skill in the art would have recognized the utility of varying amounts of polypropylene and styrene butylene ethylene styrene in the middle layer to obtain the desired softening temperature. Therefore, the

softening temperature would be readily determined by through routine optimization of the amounts of polypropylene and styrene butylene ethylene styrene in the middle layer by one having ordinary skill in the art depending on the desired use of the end product as taught by Heilmann et al.

It therefore would be obvious for one of ordinary skill in the art to vary the amounts of polypropylene and styrene butylene ethylene styrene in the middle layer and therefore in the inner layer, in order to obtain the desired softening temperature, since the softening temperature would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al.

With regard to Claims 2 – 4, the proportion of the thickness represented by the middle layer is 70% (column 4, lines 8 – 17).

With regard to Claims 5 - 6, the proportion of the thickness represented by each of the outer layer and inner layer is 15% (column 4, lines 8 – 13).

With regard to Claim 7, the total thickness of the film is 130 □m (column 4, lines 8 – 13).

With regard to Claims 8 – 9, Heilmann et al fail to disclose a total thickness in the range between 170 and 230 μm. However, Heilmann et al disclose a middle layer thickness of at least 90 μm (column 4, lines 10 – 11) and teaches the selection of layer thickness to avoid deformation of the middle layer under the action of heat (column 4, lines 13 - 17). Therefore, one of ordinary skill in the art would have recognized the utility of varying the thicknesses of the layers of the film, and therefore the total thickness of the film, to limit the deformation of the middle layer as desired. Therefore, the deformation of the middle layer would be readily

determined through routine optimization of thickness by one having ordinary skill in the art depending on the end use of the product.

It therefore would be obvious for one of ordinary skill in the art to vary the thickness in order to obtain a desired limiting of the deformation of the middle layer, since the limiting of the deformation of the middle layer would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al.

With regard to Claim 18, Heilmann et al fail to disclose an outer layer having a melting point that is greater than the melting point of the inner layer. However, Heilmann et al disclose that both layers contain polymers having melting temperatures greater than 121 degrees Celsius (column 4, lines 4 - 7) and that the melting point is selected so that the outer and inner layers support and stabilize the middle layer (column 3, lines 40 - 42). Therefore one of ordinary skill in the art would have recognized the utility of varying the melting temperatures of the polymers to obtain a desired stability of the middle layer. Therefore, the desired stability of the middle layer would be readily determined through routine optimization of the melting temperature of the polymers by one having ordinary skill in the art depending on the desired end use of the product. It therefore would be obvious for one of ordinary skill in the art to vary the melting temperatures of the polymers in order to obtain a desired stability of the middle layer, since the stability of the middle layer would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al.

With regard to Claim 19, Heilmann et al fail to disclose a melting point of the middle layer that is less than the melting point of the outer layer and greater than the melting point of the

inner layer. However, Heilmann et al disclose an outer and inner layer comprising polymers that have a softening temperature greater than 121 degrees Celsius and polymers that have a softening point less than 121 degrees Celsius (the layers adjacent to the central layer have a sohening temperature of greater than 121 degrees Celsius or contains polymers having a softening temperature of greater than 121 degrees Celsius, column 4, lines 4 - 7) and Heilmann et al teach that the softening temperatures are selected in order for the outer and inner layers to provide desired support to the middle layer (column 3, lines 62 – 67; column 1, lines 1 - 3). Therefore, one of ordinary skill in the art would have recognized the utility of varying the softening temperature of the components having a softening temperature less than 121 degrees Celsius to provide desired support to the middle layer. Therefore, the desired support provided to the middle layer would be readily determined through routine optimization of softening temperature by onehaving ordinary skill in the art depending on the desired end use of the product. It therefore would be obvious for one of ordinary skill in the art to vary the softening temperature of the components having a softening temperature less than 121 degrees Celsius in the outer and inner layers, and therefore the lowest melting temperature of the outer and inner layers, and therefore the melting point of the outer and inner layers, in order to provide desired support to the middle layer, since the support to the middle layer would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al.

With regard to Claims 20 - 22, the middle layer disclosed by Heilmann et al has a Vicat temperature of 55 degrees Celsius (Vicat A = 55 degrees Celsius; column 8, lines 11 - 15), which is in the range from 35 degrees Celsius to 75 degrees Celsius. Heilmann et al also disclose outer

layers and inner layers having Vicat temperatures of less than 121 degrees C, as discussed above (the layers adjacent to the central layer have a softening temperature, therefore a Vicat temperature, of greater than 121 degrees Celsius or contains polymers having a softening temperature of greater than 121 degrees Celsius; column 4, lines 4 - 7).

With regard to Claim 26, Heilmann et al also disclose a five layer film (column 3, line 62) comprising two layers having the composition of the middle layer and a layer having a polymer with a softening temperature of above 121 degrees Celsius between the two layers (column 3, lines 62 – 67; column 4, lines 1 – 3) and discloses that the outer and inner layers contain polymers having softening temperatures above 121 degrees Celsius (column 3, lines 31 - 36); Heilmann et al therefore disclose a five layer film having the multilayer structure: outer layer, middle layer, outer layer, middle layer, inner layer, with the thicknesses of the middle layers and outer layers being the sum of the thicknesses of the middle layers and outer layers.

With regard to Claim 27, Heilmann et al also disclose a seven layer film (column 3, line 62) comprising three layers having the composition of the middle layer and two layers having a polymer with a softening temperature of 121 degrees Celsius arranged between the three layers (column 3, lines 62 – 67; column 4, lines 1 – 3) and discloses that the outer and inner layers contain polymers having softening points above 121 degrees Celsius (column 3, lines 31 - 36),. Heilmann et al therefore disclose a seven layer film having the multilayer structure: outer layer, middle layer, outer layer, middle layer, outer layer, middle layer, inner layer, with the thicknesses of the middle layers and outer layers being the sum of the thicknesses of the middle layers and outer layers.

With regard to Claim 28, Heilmann et al disclose a method of producing the film comprising co - extruding the layers (column 6, lines 17 - 21).

With regard to Claims 29 – 31, the film disclosed by Heilmann et al is co – extruded as a flat film (column 6, lines 15 - 16); the film is therefore joined as a flat film, because in the process of co - extrusion the layers are joined to form the multi - layer film.

With regard to Claim 32, the film disclosed by Heilmann et al is suitable for contact with foodstuffs (column 7, lines 64 - 66) and Heilmann et al discloses that the use of multi - layer films in the packaging of foodstuffs (column 1, lines 16 - 20); Heilmann et al therefore disclose a packaging comprising the disclosed film.

With regard to Claim 33, the packaging stores parenteral solutions (it is appropriately sutiable for contact with parenteral solutions', column 7, lines 64 - 67), and also stores water (it is formed into a bag which is filled with water; column 8, lines 58 - 63) and therefore stores water.

3. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable Heilmann et al (U.S. Patent No. 5,783,269) view of Collette et al (U.K. Patent 2001080) and Fujii et al (European Patent No. 0838321) and Miki et al (U.S. Patent No. 4,089,913) and further in view of Andersson et al (U.S. Patent No. 6,322,739 B1).

Heilmann et al, Colette et al, Fujii et al and Miki et al disclose packaging comprising polypropylene as discussed above. Heilmann et al, Colette et al, Fujii et al and Miki et al fail to disclose a packaging that stores fluid lipophilic emulsions.

Andersson et al teach a packaging (a container having stored fluid; column 4, lines 67) comprising polypropylene (column 4, lines 39 - 41) that stores fluid lipophilic emulsions

(column 3, lines 20 - 23) for the purpose of obtaining a package having good compatibility with fluid lipid emulsions (column 3, lines 20 - 21). One of ordinary skill in the art would therefore have recognized the advantage of providing for the packaging of Andersson et al that stores fluid lipophilic emulsions, in Heilmann et al, Colette et al, Fujii et al and Miki et al, which is a packaging comprising polypropylene, depending on the desired compatibility of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a packaging that stores fluid lipophilic emulsions in Heilmann et al, Colette et al, Fujii et al and Miki et al in order to obtain a package having good compatibility as taught by Andersson et al.

ANSWERS TO APPLICANT'S ARGUMENTS

4. The declaration filed on August 1, 2006 under Rule 1.132 has been considered but has not been found to be persuasive for the reasons set forth below.

Applicant states on page 2 of the declaration, that one of ordinary skill in the art would not have had an expectation of success in combining the polymers of Heilmann et al with the polymers of Collette et al.

However, as stated above, it would have been obvious for one of ordinary skill in the art to have provided for the polypropylene of Collette et al as the polypropylene of Heilmann et al; therefore, a combination of the polymers of Heilmann et al with the polymers of Collette et al is not proposed.

Applicant also argues on page 2 that examples of the present specification fulfill the criteria of Heilmann et al, and the films show a yield point.

However, the current prior art is a combination of Heilmann et al and Collette et al; furthermore, a film having no yield point is taught by Collette et al.

Applicant also argues, on page 3, that polypropylene homopolymers have a different chemical structure from Collette et al, and that one of ordinary skill in the art would have been motivated to select a random copolymer.

However, it is unclear why one of ordinary skill in the art would be motivated to select a random copolymer; furthermore, Collette et al teach the making of the polymer by polymerizing propylene and therefore discloses polypropylene homopolymer (page 2, lines 61 – 65).

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc A Patterson whose telephone number is 571-272-1497. The examiner can normally be reached on Mon - Fri 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marc Patterson 10/16/06
Marc A. Patterson, PhD.
Primary Examiner
Art Unit 1772